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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,690	07/02/2003	Charles Webb	GC-516	4412
7590	08/03/2005		EXAMINER	
David P Gordon Gordorn & Jacobson, P.C. 60 Long Ridge Road Suite 407 Stanford, CT 06902			NGUYEN, SANG H	
			ART UNIT	PAPER NUMBER
			2877	
DATE MAILED: 08/03/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

HA

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/612,690	WEBB, CHARLES	
	Examiner Sang Nguyen	Art Unit 2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 July 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 06/02/05 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 9-27 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/17/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Response to Amendment and Election/Restriction***

Applicant's response to Election/restriction that Applicant's election without traverse of Group II (claims 9-18 and add new claims 19-27) in the reply filed on 06/02/05 is acknowledged. Further, Applicant's amendment on 06/02/05 has been entered. It is noted that the application contains claims 9-27 and claims 1-8 have been canceled by the amendment on 06/02/05.

### ***Drawings***

Figures 1-3 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: the reference "10", the reference "13", and the reference "18" as shown in the specification are not mentioned in the drawing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should

include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "**a data communication device adapted for bi-directional data communication to an external host system**" in claim 27 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention.. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

*20, 21, & 25*  
Claim 19 ~ rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (U.S. Patent No. 5,673,533).

**Regarding claim 19;** Wang et al teaches an apparatus for testing seal integrity of a package (54 of figure 6-7 and col.4 lines 53-60), the apparatus comprising:

a housing considered to be a container (40 of figure 5) that supports a medical packaging device considered to be a product (48 of figure 5 and coll.38-42) that forms a seal on the container (40 of figures 3-4) of the package (41 of figures 3-5), a peel testing device considered to be a sheet of lid stock material (42 of figures 3-4) for pulling apart

the seal and collects data relevant thereto (figures 3-4 and 12-13), and a microprocessor (58 of figure 6) in communication with the product (48 of figure 5) of the container (40 of figures 3-5) in the array packages (41 of figures 3-5) and said peel testing device considered to be a sheet of lid stock material (42 of figures 3-5). Wang et al teaches all of features of claimed invention except for a medical package device.

**Regarding claim 20;** Wang et al teaches about a cutting mechanism (52 of figures 5 and 14) for cutting a sample (48 of figure 5) of container (40 of figure 5) from the package (41 of figures 3-4).

**Regarding claim 21;** Wang et al discloses the peel testing device (figure 11) including a clamping mechanism (72, 74 of figure 11) for holding the sample (48 of figure 5) in the container (40 of figure 11).

**Regarding claim 22 and 25;** Wang et al teaches of the microprocessor (58 of figure 6) is coupled to a optical sensor (60 of figures 6 and 11) for detecting prompt the peel test (42 of figure 11) upon medical packing device (40, 41 of figures 11 and 14) for performing a predetermined number of seal forming operations (figures 5, 11 and 14).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 9-10, 12-15, 23-24 and 36-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (U.S. Patent No. 5,673,533) in view of Albrecht (U.S. Patent No. 6,763,728).**

**Regarding claims 23-24;** Wang et al teaches all of features of claimed invention except for the microprocessor for analyzing the data communicated from the peel tester device to ascertain compliance of seal and to communicate to a user an indication of compliance and the microprocessor for selecting enable the medical packing device in accordance with results of analysis of the data communication from the peel tester. However, Albrecht teaches that it is known in the art to provide an evaluation of peel test results comprising the microprocessor (14 of figure 1) coupled to an user interfaces (18 of figure 1), for analyzing the data communicated a seal testing device (12 of figure 1) wherein the seal testing device (12 of figure 1) having the peel tester device (col.4 lines 3539) to ascertain compliance of seal and to communicate to a user an indication of compliance and the microprocessor (14 of figure 1) for selecting enable the medical packing device in accordance with results of analysis of the data communication from the peel tester (col.32 lines 5-50, col.4 lines 24-65, and col.5 lines 25-65; and see figures 1-9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine apparatus for testing seal integrity of a package of Wang et al with the microprocessor for analyzing the data communicated from the peel tester device to ascertain compliance of seal and to communicate to a user an indication of compliance and the microprocessor for selecting enable the medical packing device in accordance with results of analysis of the data communication from

the peel tester as taught by the Albrecht for the purpose of protecting the contents of the package from damage or spoilage.

**Regarding claims 26-27;** Wang et al teaches all of features of claimed invention except for a handheld computing device and a data communication device adapted for bi-direction data communication to an external host system. However, Albrecht teaches that it is known in the art to provide a handheld computing device considered to be user interfaces (18 of figure 1) and a data communication device (16 of figure 1) adapted for bi-direction data communication to an external host system (14 of figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine apparatus for testing seal integrity of a package of Wang et al with a handheld computing device and a data communication device adapted for bi-direction data communication to an external host system as taught by the Albrecht for testing and evaluating a plurality of peel tests on packages having different seal integrities of seal packages.

**Regarding claim 9;** Wang et al teaches a system for testing seal integrity of seal packages (41 of figures 3-4 and 10 and col.2 lines 57-60) comprising:

    a medical packaging device considered to be a sample product (48 of figure 5) for filling on a container (40 of figures 3-5);  
    a peel tester considered to be a sheet of lid stock material (42 of figures 3-4) integral seal with the container (40 of figures 3-5) said medical packaging product (48, 40 of figure 5);

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a microprocessor (58 of figure 6) communicating the container (40 of figure 4) of the package (41 of figure 4) and a sheet of lid stock material (42 of figures 3-4) within said medical packaging product (40, 48 of figure 5) coordinating with said peel tester (42 of figures 3-4 and 11); and

a cutting mechanism considered to be a die cutting (52 of figure 5) for cutting each of said peel tester or medical packaging product (40, 48 of figure 5) of the package (41 of figures 3-4), wherein said medical packaging product (40, 48 of figure 5) prompts an operator to test a sample of said sealed packages (figures 5 and 14), wherein a sample product (48 of figures 5 and 14) is removed from said medical packaging container(40 of figure 5) and cut to a predetermined size (figures 5 and 14 by the die cutting (52 of figures 5 and 14). See figures 1-17.

Wang et al teaches all of features of claimed invention except for wherein said peel tester collects seal integrity data and shares said data with said microprocessor; and wherein said microprocessor analyzes said data in correlation to set standards. However, Albrecht teaches that it is known in the art to provide an evaluation of peel test results comprising the microprocessor (14 of figure 1) coupled to an user interfaces (18 of figure 1) for collecting and analyzing the seal integrity data communicated a seal testing device (12 of figure 1) to set standards (col.2 lines 5-53see figures 4-7), wherein the seal testing device (12 of figure 1) having the peel tester device (col.4 lines 35-65). See figures 1-9.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine apparatus for testing seal integrity of a

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package of Wang et al with said peel tester collects seal integrity data and shares said data with said microprocessor; and wherein said microprocessor analyzes said data in correlation to set standards as taught by the Albrecht for the purpose of protecting the contents of the package from damage or spoilage.

**Regarding claims 10 and 12;** Wang et al teaches about an optical sensing device (60 of figure 11) located adjacent to a seal platen (42 of figure 11) of the medical package container (40 of figure 11).

**Regarding claim 13;** Wang et al discloses wherein said medical packaging container (40 of figure 5 and 14) stops operation and notifies an operator when a breach in a seal is recognized by said sensing device (60 of figure 11 and 14).

**Regarding claims 14-15;** Wang teaches all of features of claimed invention except for a handheld computing device and a modem. However, Albrecht teaches that it is known in the art to provide a handheld computing device and a modem considered to be an user interfaces (18 of figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine apparatus for testing seal integrity of a package of Wang et al with a handheld computing device and a modem as taught by the Albrecht for the purpose of determining accuracy the value of the peel test parameters for seal package.

**Claim 11 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al in view of Albrecht as applied to claim 9 above, and further in view of Sites et al (U.S. Patent No. 5,515,159 submitted by Applicant).**

**Regarding claim 11;** Wang et al in view of Albrecht teaches all of features of claimed invention except for the optical sensing device is a multi-spectrum light. Sites teaches that it is well known in the art to provide the optical sensing device (36-1, 36-2 of figure 7) is a multi-spectrum light from a light source (18, 124 of figure 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine apparatus for testing seal integrity of a package of Wang et al with the optical sensing device is a multi-spectrum light as taught by the Sites et al for the purpose of easily detecting the existence of any defects in the seal between a container and the lid cover.

**Regarding claims 16-18;** Wang et al in view of Albrecht teaches all of features of claimed invention except for a visual inspection unit is internally located adjacent a platen of said medical packaging device. However, Sites teaches that it is well known in the art to provide a visual inspection unit (figure 1 and col.1 lines 5-10) is internally located adjacent a platen (16 of figure 1) of said medical packaging device or container (14 of figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine apparatus for testing seal integrity of a package of Wang et al with a visual inspection unit is internally located adjacent a platen of said medical packaging device as taught by the Sites et al for the purpose of analyzing located any flaws relatives to location on the package and determining the type and severity of each defect for accept or rejects.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Parker (6687622) discloses leak detection apparatus; Stauffer (6840108) discloses method and apparatus for airborne ultrasonic testing of package and container seal; Debbs et al (6622864) discloses moisture resistance package for strong sterile items; MacKenzie et al (5830547) discloses peel open package; Dey et al (5709067) discloses method for making sterile suture packages; Foslien (5379895) discloses package for surgical device; Jarman et al (5372042) discloses ultrasonic inspection of seal integrity of bond lines in sealed containers; Mally et al (5226316) discloses Package leak detection; or Leining et al (4901558) discloses seal integrity tester and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sang Nguyen whose telephone number is (571) 272-2425. The examiner can normally be reached on 9:30 am to 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on (571) 272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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*SN*

Sang Nguyen/SN

July 27, 2005

*[Handwritten Signature]*  
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*2 Aug 05*